Evidence-based Practice Center Systematic Review Protocol

Project Title: Strategies To Reduce Cesarean

I. Background and Objectives for the Systematic Review

Recent reports by the Consortium on Safe Labor, including 19 hospitals, show that the rate of cesarean birth among nulliparous women has risen to more than 30 percent.[1] The March 2010 Data Brief from the National Center for Health Statistics, titled "Recent Trends in Cesarean Delivery in the United States," reports on trends in cesarean delivery from 1991–2007.[2] During that period, the rate of cesarean birth rose to 32 percent, an increase of 53 percent, the highest rate ever reported in the United States.[2] In 2007, 1.4 million cesarean sections were performed, representing almost one-third of U.S. births.[2] HealthyPeople 2010 included an objective (16-9 in the report) to "[r]educe cesarean births among low-risk (full term, singleton, vertex presentation) women," including women giving birth for the first time and women who have had a prior cesarean birth.[3] The baseline percentage of cesarean births among primiparous women in 1998 was 18 percent, with a 2010 target of 15 percent. This objective has not been met, according to a Centers for Disease Control and Prevention report on the 1990–2003 trends in cesarean birth rates for first births among low-risk women.[4] This report noted a cesarean birth rate of 27.1 percent among primiparous women and a rate of 23.6 percent among low-risk primiparous women in 2003; the rate was found to have decreased from 1990–1996 and increased from 1996–2003.[4] As part of the current process to define Healthy People 2020 goals, this unmet objective has been proposed for retention.

The Joint Commission has expressed concern about U.S. cesarean birth rates as a performance measure in its *Specifications Manual for Joint Commission National Quality Core Measures*, noting that, "There are no data that higher rates improve any outcomes, yet the CS [cesarean section] rates continue to rise."[5] The cesarean birth rate varies considerably by geographic region (ranging from 25% to 38% among different U.S. States) and also by race/ethnicity, maternal age, and other factors, with the highest rates in the southeastern States.[2] One 2007 author analyzing data on cesarean births from a large U.S. hospital system described the rate variation (ranging from 9% to 37% for primary cesarean births) as "suggest[ing] a pattern of almost random decision making" and "reflect[ing] a lack of sufficient reliable, outcomes-based data to guide clinical decisionmaking."[6] The recent National Institutes of Health Consensus Development Conference, "Vaginal Birth After Cesarean: New Insights," also generated considerable popular interest and media coverage and included a discussion of the role of the rate of primary cesareans.[7]

Most studies relevant to cesarean birth do not focus explicitly on reducing or affecting the rate (there a few exceptions, such as studies of a mandatory second opinion or obstetric peer review). Our comparative effectiveness review will include published literature that also implicitly includes reducing the rate of cesarean birth as an aim. Evidence from relevant randomized controlled trials (RCTs) is primarily garnered from studies of specific strategies (such as methods of induction) with the cesarean birth rate as a primary or secondary outcome (mainly in low-risk women), but these studies have not focused on interventions implemented specifically to affect the rate. Similarly, large observational trials involving large patient

populations have focused only on identifying multiple risk factors (including sociodemographic factors and birth-related interventions) associated with cesarean birth.

Numerous meta-analyses and systematic reviews (particularly Cochrane Collaboration products) exist on specific maternal characteristics and intrapartum care methods, including maternal body mass index and obesity, pushing and birthing position, fetal monitoring, pain relief, walking during labor, active management of labor, and induction and augmentation. These reviews include products developed for the Agency for Healthcare Research and Quality that focus on cesarean birth, maternal request, elective induction, and outcomes of maternal weight gain. However, the existing literature on cesarean birth lacks systematic reviews that attempt to synthesize these numerous factors into a single review document.

The National Center for Health and Clinical Excellence in the United Kingdom developed guidelines in 2004 on cesarean birth, intrapartum care, antenatal care, and induction of labor that address the effects of some practices on cesarean birth rates.[8] These guidelines, which are currently being updated, were developed by using the process outlined in The Guideline Development Process—Information for National Collaborating Centres and Guideline Development Groups and included a systematic review of the published literature.[9] Major relevant recommendations include the following:

- Inclusion of evidence-based information about cesareans during the antenatal period.
- Consent for cesarean after provision of evidence-based information.
- Documented urgency of the cesarean using a standardized scheme.

Cesarean birth is an active area of ongoing research. Six open, active trials were identified in ClinicalTrials.gov that included cesarean birth rate as a primary outcome in two and as a secondary outcome in four others. These trials focus almost exclusively on interventions related to maternal weight gain, including exercise, nutritional counseling, and lifestyle counseling, with additional trials on acupuncture for prevention of post–due date pregnancy, and intravenous fluid during labor. Many completed studies, for which no results were available, were also identified. These studies included trials on the effects of doula care but focused primarily on labor analgesia and induction.

Scan of the Literature

The RCTs we identified that had cesarean birth rate as a primary or secondary outcome included the following interventions: diet and lifestyle counseling to prevent weight gain during pregnancy (1 RCT); prenatal and antenatal education and preparation, including interventions to reduce maternal fear/anxiety (4 RCTs); exercise (1 RCT); fetal monitoring (9 RCTs); food/fluid intake during labor (3 RCTs); pain relief, primarily with epidural analgesia (20 RCTs); pushing and delivery position (3 RCTs); support during labor (6 RCTs); induction (>70 RCTs), augmentation (4 RCTs), cervical ripening (20 RCTs), and combinations of these three interventions; and other miscellaneous topics (13 RCTs), such as tub bathing during labor, partogram use policies, and obstetric peer review. We included these trials, even if the interventions had no effect on the cesarean birth rate. Additional nonrandomized controlled trials that had cesarean rate as a primary or secondary outcome (6 trials) were also identified. There also were a considerable number of observational studies that included the cesarean birth rate as

an outcome in investigating such risk factors as: fetal monitoring (1 study); induction (>20 studies); insurance type/status (9 studies); nutritional status (2 studies); provider and institutional policy concerns, including delivery setting, provider type, and professional liability insurance (>20 studies); pain relief (15 studies); sociodemographic factors, including race/ethnicity, educational status, and maternal age (>15 studies); sleep and fatigue (2 studies); maternal weight, obesity, body mass index, and height (35 studies); and miscellaneous topics, including studies examining large cohorts of women with multiple contributing risk factors (>50 studies).

Summary

A comprehensive review evaluating the effectiveness of strategies to reduce cesarean birth would address the potential benefits and harms of these strategies and risk factors that may have an effect on the rate of cesarean birth and contribute to understanding the potential benefits and harms of the current rate overall. Inaction on this topic is most likely to perpetuate the status quo and keep the rate of cesarean birth in the United States at the highest level ever reported.

II. The Key Questions

We developed the Key Questions (KQs) for this review based on input from Key Informants and experts. The questions were posted to the Effective Health Care Program Web site (www.effectivehealthcare.ahrq.gov) for public comment for approximately 4 weeks. Comments received on the posted KQs will be used in framing the report.

The comments generally supported our choice of KQs. Comments generally addressed word choices.

Based on several comments related to the use of the word "interventions" we altered the title of the review to "Strategies To Reduce Cesarean Birth" in order to clarify that the review was focused on measures to reduce cesarean.

We also reworded the KQs to specify that the subject of this review were women "who are intending a vaginal birth," therefore deleting the word "eligible" in all KQs.

Key Questions

Question 1

What strategies during pregnancy are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Question 2

What strategies during labor are effective to reduce the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Question 3

Where head-to-head comparisons are available, what strategies are shown to be superior in reducing the use of cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

Question 4

What are the nature and frequency of adverse effects resulting from strategies used to reduce cesarean birth among women, with a singleton pregnancy, who are intending a vaginal birth?

PICOTS

Population(s):

- Low-risk pregnant women who have a singleton pregnancy, a vertex presentation, at-term delivery, and no previous cesarean birth.

Strategies:

- For KQ 1, including but not limited to:
  - Childbirth education
  - External cephalic version
  - Health systems interventions (quality assurance, audit and feedback, etc.)
- For KQ 2, including but not limited to:
  - Timing of admission
  - Active management
  - Pain management
  - Labor support
  - Provider type
  - Provider education
  - Birthing center location
  - Technology use
  - Ambulation
  - Positioning
  - Feeding
  - 2nd-stage management
  - Health systems interventions (quality assurance, audit and feedback, etc.)
- For KQs 3 and 4, including but not limited to:
  - Childbirth education
  - External cephalic version
  - Timing of admission

- Active management
- Pain management
- Labor support
- Provider type
- Provider education
- Birthing center location
- Technology use
- Ambulation
- Positioning
- Feeding
- 2nd-stage management
- Health systems interventions (quality assurance, audit and feedback, etc.)

Comparators:

- For KQs 1 and 2:
  - Usual care
- For KQ 3:
  - The interventions listed above

Outcomes measures for each KQ:

- Intermediate outcomes
  - Labor progression
  - Augmentation
  - New maternal morbidity
  - Fetal monitoring
  - Failed forceps or vacuum extraction
  - Maternal coping
  - Pain management
  - Amnioinfusion
- Final outcomes
  - Route of birth
    - Cesarean
    - Vaginal (spontaneous)
    - Vaginal (assisted)
  - Maternal morbidity and mortality

Source: *www.effectivehealthcare.ahrq.gov*
Published Online: *May 6, 2011*

  - Neonatal morbidity and mortality
  - Apgar score
  - Observation in neonatal intensive care unit
  - Admission to neonatal intensive care unit
  - Maternal-infant bonding
  - Breastfeeding success
  - Maternal satisfaction

- Adverse effects of intervention(s)

  - All reported adverse events

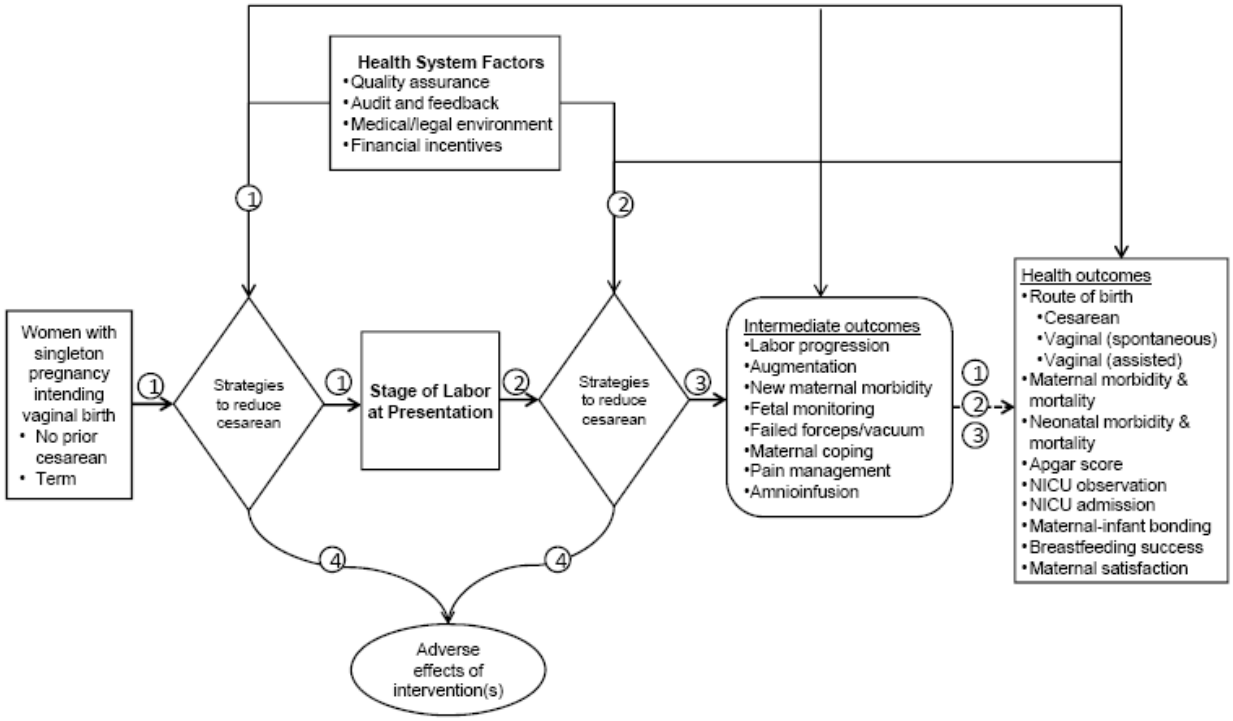
Timing:

- During pregnancy, all trimesters
- During labor, all stages
- Short-term (birth to 3 months)
- Long-term (≥3 months)

Settings:

- All health care settings will be considered, including the home, a hospital, provider offices, and/or clinic.

Figure 1. Draft analytic framework for strategies to reduce cesarean birth



III. Analytic Framework In the topmost rectangle, please delete the hyphen from "Medico-legal" to comply with AHRQ style.

Abbreviations: NICU = neonatal intensive care unit.

Source: *www.effectivehealthcare.ahrq.gov*
Published Online: *May 6, 2011*

IV. Methods

A. Criteria for Inclusion/Exclusion of Studies in the Review

Table 1 lists the inclusion/exclusion criteria we selected based on our understanding of the literature, the topic-refinement phase, input from content experts, and established principles of methodological quality.

We will only review published RCTs of strategies to reduce the rate of cesarean births or those pre- and post-studies related to health system changes to decrease the number of cesareans. In addition, studies will be included if the stated or implied aim of the study was to reduce cesarean (determined by the following criteria):

- The introduction of the paper includes a literature review of rationale, indicating interest in improving or reducing cesarean risk/rate or in influencing route of birth (vaginal, assisted, cesarean) as an outcome that would be influenced by the intervention under study.
- The stated primary or secondary aims indicate intention to examine influence of the intervention on cesarean risk/rate or route of birth.
- The analytic models indicate the authors conducted data analysis of the effect of the intervention as it relates to cesarean risk/rate or route of birth.
- The results feature data about the relationship of the intervention to cesarean risk/rate or route of birth as reporting of a primary or secondary aim.
- The tables in the results section feature data about the relationship of the strategy to cesarean risk/rate or route of birth as reporting of a primary or secondary aim.
- The discussion interprets the strategy as potentially having value for modifying cesarean risk/rates or influencing route of delivery or the authors expresses dismay that they did not find it had value for modifying cesarean risk/rates or influencing route of delivery.

Given a lack of translation resources, we will also focus the review on studies published in English; included studies may include non–U.S. populations but must be published in English. Because the growing rate of cesarean birth is an issue in the English-speaking and Western world, very few studies related to strategies to reduce cesarean will be published in other languages, and those that are will also be published in English. Given the size of the literature related to cesarean birth, our review will include RCTs and pre- and post-studies related to large-scale health systems changes. Included papers must also include data that can be found in the publication. Numbers reported in graphical or pictorial representation only will not be included or extrapolated from the presentation.

Table 1: Inclusion/exclusion criteria

Category	Criteria
Study population	Low-risk pregnant women who have a singleton pregnancy, a vertex presentation as defined by the authors where reported, at-term delivery, and no previous cesarean birth and their children
Time period	All years

Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials and pre- and post-studies related to large-scale health systems changes Other criteria • Original research studies that provide sufficient detail regarding methods and results to enable use and adjustment of the data and results • Studies must include at least one outcome measure of an outcome listed in the PICOTS • Studies must include extractable data on relevant outcomes

Abbreviations: PICOTS = population, intervention, comparator, outcome, timing, and setting.

B. Searching for the Evidence: Literature Search Strategies for Identification of Relevant Studies to Answer the Key Questions

Search the literature. We will search on topics that include various entries including, but not limited to, "cesarean," "cesarean section," "caesarean," and "c-section." In addition, we will use search terms to limit the literature to RCTs and pre- and post-studies of health systems changes. We will search primarily MEDLINE© but will also search CINAHL in order to ensure the literature includes the nursing literature.

During our reviews of abstracts and full-text articles, we will update the literature search quarterly by adding relevant updated studies as needed. We will also update the search when the draft report is submitted and add relevant studies as needed while the draft report is undergoing peer review. We will also incorporate studies that meet our inclusion criteria or are relevant as background material that may be identified by both public and peer reviewers.

We will use additional searches of the reference lists of existing systematic reviews or meta-analyses of strategies to reduce cesarean; we will also scan the reference lists of articles undergoing full-text review for studies that might meet inclusion criteria.

Grey literature will be identified by using a similar but more concise search string within Google. The results will be parsed by date and tagged as "grey literature" within the database of citations and compared to the peer-reviewed and indexed body of literature for duplication.

Initial review of abstracts. An abstract review form will be developed and pretested by all team members. It will be revised as needed before full abstract review begins. We will review all the titles and abstracts identified through our searches against our inclusion/exclusion criteria. Each abstract will be reviewed by at least two members of the investigative team. When differences between the reviewers arise, we will err on the side of inclusion. For studies without adequate information to make the determination, we will retrieve the full-text articles and review them against the inclusion/exclusion criteria.

Retrieving and reviewing articles. We will retrieve and review full-text articles that meet our predetermined inclusion/exclusion criteria or for which we have insufficient information at

the abstract phase to make a decision about eligibility. A full-text review form will be developed and pretested by all team members. Each article will be reviewed by at least two members of the investigative team. Differences will be resolved by consensus.

After reviewing a sample of relevant articles, the Methods and Content Leads will design the data-extraction forms and evidence tables for testing by the team. These forms will undergo revisions as needed until the team is satisfied that they are appropriate; the forms then will be used to extract data from all full-text articles that meet inclusion criteria.

We will develop a simple categorization scheme for coding the reasons that articles, at the stage of full review, are not finally included in the report. The abstractor will note the reason for exclusion on the article cover page. We will then record that code in an EndNote® (Thomson Reuters, New York, NY) bibliographic database so that we can later compile a listing of excluded articles and the reasons for such exclusions.

C. Data Abstraction and Data Management

Deciding which outcomes are to be extracted. With our Technical Expert Panel, we identified critical outcomes related to strategies to reduce cesarean birth. We will capture all relevant outcome measures available and report them as part of the data extraction and analysis. With such a variation in available strategies, it is ideal to remain flexible about which outcomes are sought in order to capture and utilize as much data as possible. For example, we will report all reported outcomes such as maternal coping and maternal-infant bonding, as authors will report this outcome in various methods and by differing modes.

D. Assessment of Methodological Quality of Individual Studies

Assessing study quality. The quality of individual studies will be assessed by using specific assessment tools for each type of study. Data from studies that are considered to be fair or good will be included in the analysis. Poor studies will be identified but not included in the data analysis for the relevant KQ. For RCTs, the fundamental domains will include: adequate sequence generation, allocation concealment, blinding, incomplete outcome data addressed, and freedom from selective reporting bias. For observational studies (specifically the pre- and post-studies of health systems changes), we will assess three broad characteristics: 1) the selection of the study groups; 2) the comparability of the study groups; and 3) the outcome of interest. For example, for a cohort study, the fundamental criteria will include: representativeness of the cohort, selection of a nonexposed cohort, ascertainment of treatment exposure, outcome of interest, comparability of cohorts, assessment of outcome, adequate duration of followup, and adequate followup of the cohort. Other sources of bias would include imbalances in baseline measures, source of funding, stopping treatment early for benefit, and appropriateness of crossover design. Decision rules regarding detailed use of the quality-assessment tools will be specified a priori by the review team. Two senior staff will independently perform quality assessment of the included studies; disagreements will be resolved through discussion or third-party adjudication as needed. We will record quality assessments in tables, summarizing each study. Studies will be given a quality grade of good, fair, or poor per the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[10]

E. Data Synthesis

Preparing evidence tables. We will enter data into evidence tables by using predetermined abbreviations and acronyms consistently across all entries. The dimensions (i.e., areas of special focus, or the columns) of each evidence table may vary by KQ as appropriate, but the tables will contain some common elements, such as author, year of publication, study location (e.g., country, city, state) and time period, population description, sample size, and study type (e.g., RCT, prospective observational study, etc.). Using methodological and statistical consultation, we will determine if the data are appropriate to conduct quantitative syntheses such as meta-analyses (i.e., lack of excessive heterogeneity).

F. Grading the Evidence for Each Key Question

Assessing the strength of evidence. We will also utilize explicit criteria for rating the overall strength of the collective evidence on each intervention into qualitative categories (e.g., low, moderate, high, insufficient).

The strength of evidence evaluation will be that stipulated in the *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*,[10] which emphasizes the following four major domains: risk of bias (low, medium, high), consistency (inconsistency not present, inconsistency present, unknown, or not applicable), directness (direct, indirect), and precision (precise, imprecise). Risk of bias is derived from the quality assessment of the individual studies that addressed the KQ and specific outcome under consideration. Each key outcome on each comparison of interest will be given an overall evidence grade based on the ratings for the individual domains.

The overall strength of evidence will be graded as "high" (indicating high confidence that the evidence reflects the true effect and that further research is very unlikely to change our confidence in the estimate of effect), "moderate" (indicating moderate confidence that the evidence reflects the true effect and that further research may change our confidence in the estimate of effect and may change the estimate), "low" (indicating low confidence that the evidence reflects the true effect and that further research is likely to change our confidence in the estimate of effect and is likely to change the estimate), or "insufficient" (indicating that evidence is either unavailable or does not permit estimation of an effect).[11] When no studies are available for an outcome or comparison of interest, the evidence will be graded as insufficient.

Two senior staff will independently grade the body of evidence; disagreements will be resolved as needed through discussion or third-party adjudication. We will record strength of evidence assessments in tables, summarizing for each outcome.

G. Assessing Applicability

Our team will assess the applicability of the results gathered from the literature according to methods guidance for Evidence-based Practice Centers. This will be done to account for any factors limiting the ability to apply interventions to other populations or other settings, such as inadequate description of the intervention or failure to report follow-up data.

V. References

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11. Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—Agency for Healthcare Research and Quality and the Effective Health-Care Program. J Clin Epidemiol 2010;63:513-23.

VI. Definition of Terms

Not applicable.

VII. Summary of Protocol Amendments

In the event of protocol amendments, the date of each amendment will be accompanied by a description of the change and the rationale.

VIII. Review of Key Questions

For all EPC reviews, key questions were reviewed and refined as needed by the EPC with input from Key Informants and the Technical Expert Panel (TEP) to assure that the questions are specific and explicit about what information is being reviewed. In addition, for Comparative

Effectiveness reviews, the key questions were posted for public comment and finalized by the EPC after review of the comments.

IX. Key Informants

Key Informants are the end users of research, including patients and caregivers, practicing clinicians, relevant professional and consumer organizations, purchasers of health care, and others with experience in making health care decisions. Within the EPC program, the Key Informant role is to provide input into identifying the Key Questions for research that will inform healthcare decisions. The EPC solicits input from Key Informants when developing questions for systematic review or when identifying high priority research gaps and needed new research. Key Informants are not involved in analyzing the evidence or writing the report and have not reviewed the report, except as given the opportunity to do so through the peer or public review mechanism.

Key Informants must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their role as end-users, individuals are invited to serve as Key Informants and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

X. Technical Experts

Technical Experts comprise a multi-disciplinary group of clinical, content, and methodologic experts who provide input in defining populations, interventions, comparisons, or outcomes as well as identifying particular studies or databases to search. They are selected to provide broad expertise and perspectives specific to the topic under development. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore study questions, design and/or methodological approaches do not necessarily represent the views of individual technical and content experts. Technical Experts provide information to the EPC to identify literature search strategies and recommend approaches to specific issues as requested by the EPC. Technical Experts do not do analysis of any kind nor contribute to the writing of the report and have not reviewed the report, except as given the opportunity to do so through the public review mechanism.

Technical Experts must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Because of their unique clinical or content expertise, individuals are invited to serve as Technical Experts and those who present with potential conflicts may be retained. The TOO and the EPC work to balance, manage, or mitigate any potential conflicts of interest identified.

XI. Peer Reviewers

Peer reviewers are invited to provide written comments on the draft report based on their clinical, content, or methodologic expertise. Peer review comments on the preliminary draft of the report are considered by the EPC in preparation of the final draft of the report. Peer reviewers do not participate in writing or editing of the final report or other products. The synthesis of the scientific literature presented in the final report does not necessarily represent the views of individual reviewers. The dispositions of the peer review comments are documented and will, for CERs and Technical briefs, be published three months after the publication of the Evidence report.

Potential Reviewers must disclose any financial conflicts of interest greater than $10,000 and any other relevant business or professional conflicts of interest. Invited Peer Reviewers may not have any financial conflict of interest greater than $10,000. Peer reviewers who disclose potential business or professional conflicts of interest may submit comments on draft reports through the public comment mechanism.

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